IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

KATHERINE CROCKETT, **Plaintiff,** **v.** **LUITPOLD PHARMACEUTICALS, INC.; AMERICAN REGENT, INC.; DAIICHI SANKYO, INC.; DAIICHI SANKYO US HOLDINGS, INC.; and VIFOR (INTERNATIONAL) AG,** **Defendant.**	**CIVIL ACTION** **NO. 19-276**

MEMORANDUM OPINION

This drug product liability case, one among many brought against Defendants by separate plaintiffs, arises out of the alleged injuries Plaintiff Katherine Crockett sustained after being administered Injectafer, an iron-replacement medication used to treat iron deficiency anemia. Plaintiff attributes her injuries to hypophosphatemia ("HPP"), a condition marked by low blood phosphorus levels. Plaintiff brings claims for negligence, negligent failure to warn, negligent design defect, negligent misrepresentation, and fraud, arguing, in relevant part, that the labeling for Injectafer failed to properly warn of the risks of HPP and that Defendants failed to exercise reasonable care in the testing, monitoring, and pharmacovigilance practices associated with the product.

Defendants[1] move to exclude the expert testimony of Plaintiff's expert George Samaras, Ph.D., pursuant to Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharms., Inc.*, 509

[1] Luitpold Pharmaceuticals, Inc. merged with American Regent, Inc., and the surviving entity was renamed American Regent, Inc. On that basis, Defendants refer only to American, Regent, Inc. in referring to the two former entities.

U.S. 579 (1993).

For the reasons below, Defendants' motion will be granted in part and denied in part.

I. FACTUAL BACKGROUND[2]

Plaintiff's proposed regulatory expert George Samaras, Ph.D., is a biomedical scientist and interdisciplinary engineer whose "interest, expertise, and focus are medical product development across the full product lifecycle[.]" Samaras has two doctoral degrees, one in engineering management and another in physiology.[3] He also has a number of licenses and certifications, including as to ergonomics and electrical/software engineering.

In his professional life, he has worked in different capacities on medical devices, including as to "health information systems and pharmaceutical container closure systems for combination medical devices." He currently heads a private engineering practice "involved in software engineering, human factors[4] engineering, computer systems validation, quality engineering, technical management consulting, expert testimony, and occupational &

[2] The broader factual and procedural background to the case is omitted for sake of brevity and in light of the parties' familiarity with the case.

[3] "Engineering management," as Samaras describes in his curriculum vitae, is a "subdiscipline of Industrial Engineering." His area of study in industrial engineering was focused on "organizational effectiveness."

As for his physiology background, his area of study was "mammalian physiology & pharmacology," and his dissertation focused on "central nervous system neuronal transcellular reuptake mechanisms."

[4] "Human factors" is defined by Merriam Webster alternatively as "ergonomics," which in turn is defined as "an applied science concerned with the characteristics of people that need to be considered in designing and arranging things that they use in order that people and things will interact most effectively and safely." *Ergonomics*, Merriam-Webster's Unabridged Dictionary, https://unabridged.merriam-webster.com/unabridged/ergonomics (last visited February 16, 2023); *see also Okanovic v. Hayes*, 2019 WL 5692754, at *3 (M.D. Pa. Nov. 4, 2019) ("Human factors (or ergonomics) is the scientific discipline concerned with the understanding of interactions among humans and other elements of a system, and the profession that applies theory, principles, data, and other methods to design in order to optimize human well-being and overall system performance." (internal quotation and citation omitted)).

environmental health & safety research."

Overall, he has "extensive experience (nearly four decades) working with regulated organizations," during which he has assisted clients in developing quality management systems and obtaining premarket approvals from the FDA, as well as assisting them "in a variety of postmarket activities, with an emphasis on postmarket risk management."

Samaras submitted a 156-page report, wherein he opines on, *inter alia*, the adequacy of Defendants' labeling for Injectafer and Defendants' pharmacovigilance system (*i.e.*, the practices designed to manage the risks posed by the drug).[5] Specifically, Samaras concludes the following:

- "Defendants did not engage in *effective hazard communication* for US prescribers and US consumers;"
- "Defendants did not implement an *effective pharmaceutical risk management system* to protect US prescribers and US consumers;"
- "Defendants did not use an *effective pharmacovigilance system* that would reliably manage serious and catastrophic injuries associated with the use of the Injectafer;" and
- "Defendants did not have an *effective Quality Management System* for marketing prescription-only medicines."

II. LEGAL STANDARDS

Defendants' motion is governed by *Daubert*, 509 U.S. 579, which established a "gatekeeping role" for trial courts in admitting expert testimony. *Oddi v. Ford Motor Co.*, 234 F.3d 136, 144 (3d Cir. 2000) (quoting *Daubert*, 509 U.S. at 597). The *Daubert* standard is codified in Federal Rule of Evidence 702, which provides:

A witness who is qualified as an expert by knowledge, skill, experience, training,

[5] "Pharmacovigilance" is defined as "the monitoring, evaluation, and prevention of adverse effects associated with the administration of medicines." *Pharmacovigilance*, Merriam-Webster's Medical Dictionary, https://unabridged.merriam-webster.com/medical/pharmacovigilance (last visited February 16, 2023).

> or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702; *see Durando v. Trustees of Univ. of Pennsylvania*, 2022 WL 2467080, at *1 (E.D. Pa. July 6, 2022). The rule "embodies a trilogy of restrictions on expert testimony: qualification, reliability, and fit." *Durando*, 2022 WL 2467080, at *1 (quoting *Schneider ex rel. Est. of Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003)). The proponent of expert testimony has the burden of establishing its admissibility by a preponderance of evidence. *Oddi*, 234 F.3d at 144 (citing *Daubert*, 509 U.S. at 593 n.10).

A. Qualifications

To satisfy *Daubert*'s qualification requirement, an expert must possess "specialized knowledge regarding the area of testimony." *Betterbox Comm'ns Ltd. v. BB Techs., Inc.*, 300 F.3d 325, 327 (3d Cir. 2002) (internal quotation omitted). "The basis of this specialized knowledge 'can be practical experience as well as academic training and credentials.'" *Waldorf v. Shuta*, 142 F.3d 601, 625 (3d Cir. 1998) (citing *American Tech. Resources v. United States*, 893 F.2d 651, 656 (3d Cir. 1990); and *Hammond v. International Harvester Co.*, 691 F.2d 646, 653 (3d Cir. 1982)). The qualification requirement is generally interpreted "liberally," *Pineda v. Ford Motor Co.*, 520 F.3d 237, 244 (3d Cir. 2008), and "a broad range of knowledge, skills, and training qualify an expert as such." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741 (3d Cir. 1994) (citation omitted). Nevertheless, an expert "must first be qualified by virtue of specialized expertise." *Moore v. State Farm Fire & Cas. Co.*, 2015 WL 5729266, at *1 (E.D. Pa. Sept. 30, 2015) (quoting *Elcock v. Kmart Corp.*, 233 F.3d 734, 740-41 (3d Cir. 2000)).

B. Reliability

An expert's conclusions must "reliably flow from the facts known to the expert and the methodology used." *Oddi*, 234 F.3d at 146 (citation omitted). "To satisfy the reliability requirement, 'the expert must have good grounds for his or her belief,' not 'subjective belief or unsupported speculation.'" *T.N. Incorporation, Ltd. v. Fid. Nat'l Info. Servs., Inc.*, 2021 WL 5980048, at *2 (E.D. Pa. Dec. 17, 2021) (quoting *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d at 742). For testimony such as Samaras's, which does not involve the sort of strict "scientific knowledge" at issue in *Daubert* inasmuch as he opines on regulatory issues and risk management practices, reliability concerns typically "focus upon personal knowledge or experience." *Durando*, 2022 WL 2467080, at *2 (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999)); *cf. In re Paoli R.R. Yard PCB Litig.*, 35 F.3d at 742 n.8 (summarizing *Daubert* reliability factors typically applied to testimony involving scientific methods). The "reliability analysis applies to all aspects of an expert's testimony," including "the link between the facts and the conclusion." *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 155 (3d Cir. 1999). "The reliability test is flexible and a district court enjoys 'broad latitude when it decides how to determine reliability.'" *Durando*, 2022 WL 2467080, at *2 (quoting *Kumho Tire*, 526 U.S. at 142). When reliability questions go to the weight of an expert's proposed testimony rather than its admissibility, they become an issue suitable for the jury. *See id.* at *4.

C. Fit

"In assessing whether an expert's proposed testimony fits, [the question is] whether the expert testimony proffered is sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute." *United States v. Schiff*, 602 F.3d 152, 173 (3d Cir. 2010) (internal quotation, ellipses, and citation omitted). The fit of testimony goes "primarily to relevance."

Daubert, 509 U.S. at 591. Relevancy presents a "relatively low obstacle to clear." *Hausknecht v. John Hancock Life Ins. Co. of New York*, 2022 WL 1664362, at *8 (E.D. Pa. May 25, 2022) (citing *United States v. Ford*, 481 F.3d 215, 219-20 (3d Cir. 2007)). "The Rules of Evidence embody a strong preference for admitting any evidence that may assist the trier of fact." *Pineda*, 520 F.3d at 243 (citation omitted).

III. DISCUSSION

Defendants, while moving to exclude the whole of Samaras's testimony, focus on two topics of Samaras's report: the purported inadequacy of the Injectafer labeling and Defendants' pharmacovigilance program. Defendants argue that Samaras's testimony on these topics violates each of Rule 702's trilogy of requirements for admissibility.

A. Opinions Drawing Legal Conclusions Will Be Excluded

In addition to the two topics of testimony identified by Defendants as objectionable, there is preliminary issue to be addressed. Samaras draws a number of impermissible legal conclusions bearing on the issues in this case in his expert report. For instance, Samaras opines, *inter alia*, that "US federal regulations controlling drug labeling were improperly followed"; "repeated failures to update the labeling, rendering it false & misleading . . . meets the definition of the regulatory term 'misbranded'"; and "Defendants' activities, decisions, conduct, and omissions *fall below the standard of care*." Expert witnesses are "prohibited from rendering a legal opinion." *Berckeley Inv. Grp., Ltd. v. Colkitt*, 455 F.3d 195, 217 (3d Cir. 2006). "While Rule 704 allows experts to provide an opinion about the 'ultimate issue' in a case, it prohibits experts from opining about the ultimate legal conclusion or about the law or legal standards." *Patrick v. Moorman*, 536 F. App'x 255, 258 (3d Cir. 2013) (citations omitted). Samaras is not permitted to render legal opinions in his testimony. As such, any testimony drawing a legal

conclusion will be excluded.

B. Samaras Lacks Qualifications to Opine on Injectafer Prescription Drug Labeling

Defendants object to Samaras's opinions on the "purported inadequacy of the Injectafer Label" in part on the grounds he lacks qualifications to opine on prescription drug labeling. For instance, Samaras states, *inter alia*, that the labeling was "false & misleading" and that the "full prescribing information (FPI) was defective," listing various defects, such as "Missing/late Warnings & Precautions and anti-warnings." In light of the labeling defects he identifies, Samaras concludes that "Defendants did not engage in *effective hazard communication* for US prescribers and US consumers" and "US federal regulations controlling drug labeling were improperly followed" (the latter being impermissible in any case as drawing a legal conclusion, *see supra*).[6]

The adequacy of a prescription drug label is governed by a complex regulatory regime. *See, e.g.*, *In re Fosamax (Alendronate Sodium) Prod. Liab. Litig.*, 593 F. Supp.3d 96, 105 (D.N.J. 2022) ("[L]abeling is the 'centerpiece' of the FDA's risk management strategy for approved drugs, and the primary means by which the FDA communicates its conclusions about drug safety to the public.") (citation omitted); *see id.* ("The FDA closely regulates the safety information on drug labels, down to the exact text of warnings."); *see also, e.g.*, 21 C.F.R. § 201.56 (requirements on the content and format of labeling for human prescription drug products).

In light of the regulatory regime governing prescription drugs, Plaintiff has not demonstrated that Samaras is qualified to render opinions on the sufficiency of the information

[6] As Samaras explains in his report, "ineffective hazard communication" is a translation for "failure to warn" in "human factors engineering terms."

on the Injectafer label—*i.e.*, render opinions on "effective hazard communication" (in his terms) in respect to the contents of the label. Though offered as Plaintiff's regulatory expert, Samaras does not have relevant regulatory experience concerning prescription drugs to qualify him to render an opinion on whether Injectafer's label was adequate or complied with FDA regulations.

Specifically, while he worked for roughly 6 years at the FDA (or one of its predecessors), he worked on electronics and software activities. His work did not concern prescription drugs. Nor has his work since involved prescription drugs, except perhaps in respect to drug container systems—*i.e.*, packaging—or by serving as an expert witness in pharmaceutical cases).[7] Samaras's background and experience in human factors engineering, ergonomics, software engineering, and medical devices does not, without more, qualify him to opine on the adequacy of prescription drug labels. His area of expertise, even if it broadly concerns regulatory affairs and risk management, is too far removed from the topic of prescription drug labels to qualify him to opine on their regulatory adequacy. As he himself affirmed in his deposition testimony, outside of serving as an expert in some pharmaceutical litigation, he has not "completed any work to develop expertise in the pharmaceutical regulations."[8]

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[7] While Plaintiff contends that Samaras has "focused on medical product development, including prescription drugs," the cited portion of the record does not support the contention that Samaras has worked on prescription drug labeling. Moreover, while stating that Samaras "has consulted on pharmaceuticals in at least three matters," Plaintiff does not explicitly identify what cases those were or what they involved, and the portion of the record Plaintiff cites to does not support Plaintiff's statement that he has consulted in at least three such matters. (It appears that Plaintiff may be referring in part to *Wolfe v. McNeil-PPC, Inc.*, 2011 WL 1673805, at *11 (E.D. Pa. May 4, 2011), which Plaintiff cites elsewhere, but *Wolfe* did not involve prescription drugs; rather, it involved an over-the-counter medication.) Other than these conclusory statements, Plaintiff does not otherwise attempt to fill out the gap in Samaras's experience concerning prescription drug labeling.

[8] While Plaintiff cites to *Pennsylvania Tr. Co. v. Dorel Juv. Grp., Inc.*, 851 F. Supp.2d 831, 837 (E.D. Pa. 2011) in support of the proposition that "[e]xperts are permitted to gain experience in a specific area solely for the purposes of litigation" (relying on the fact that Samaras has some experience with prescription drugs garnered through serving as an expert witness), *Pennsylvania Trust* is distinguishable. There, plaintiff sought to limit the testimony of an expert in respect to "child seat design" because his expertise on that issue was developed "solely for litigation." *Id.* at 837. The court concluded that the expert's background and experience nonetheless qualified him to offer an expert opinion on the child seat design, finding his "training as a mechanical engineer" supported his qualification

Given these shortcomings, Plaintiff has not demonstrated he has expertise concerning FDA regulation of prescription drug labeling. *Cf. Rowland v. Novartis Pharms. Corp.*, 9 F. Supp.3d 553, 561 (W.D. Pa. 2014) (allowing expert "to testify as to the general FDA regulatory scheme governing pharmaceutical drugs due to her significant experience with the FDA and its regulations regarding new drug application, approval, monitoring, and labeling."); *see also In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prod. Liab. Litig.*, 2000 WL 962545, at *3 (E.D. Pa. June 28, 2000) ("[A] court should exclude proffered expert testimony if the subject of the testimony lies outside the witness's area of expertise." (internal quotation and citation omitted)).[9]

For these reasons, Samaras's testimony regarding the sufficiency of Injectafer's label will be excluded on the grounds he is not qualified to opine on the adequacy of prescription drug labeling or prescription drug labels' compliance with FDA regulations.[10] Plaintiff has not demonstrated that Samaras's experience in software, electrical, or human factors engineering provides relevant grounds of expertise to opine on prescription drug labeling.

(the expert had "three degrees in mechanical engineering"). *Id.* Here, Samaras's credentials and expertise are not nearly as closely related to the topic of testimony (prescription drug labeling) as the expert's background in *Pennsylvania Trust*. While a mechanical engineering background supports finding a qualification to opine on the design of a child car seat, Samaras's experience as an engineer focusing on software, electronics, and human factors/ergonomics is not sufficient to qualify him to opine on prescription drug labeling.

[9] While Plaintiff cites to *Wolfe v. McNeil-PPC, Inc.*, 2011 WL 1673805, at *11 (E.D. Pa. May 4, 2011), where the court found Samaras was qualified to evaluate the warning label on over-the-counter Children's Motrin, *Wolfe* is distinguishable on the basis it did not involve prescription drugs, which are subject to their own complex regulatory regime. Moreover, *Wolfe* is not binding precedent on this Court.

[10] To the extent that Samaras's testimony concerns the adequacy of the Injectafer label from the perspective of a prescribing physician, Plaintiff also has not demonstrated he is qualified to do so. Samaras is not a practicing physician or healthcare professional; he does not prescribe Injectafer or any similar drug to any patient; nor does he conduct research or perform clinical testing concerning Injectafer, similar drugs, or any related conditions or diseases. Indeed, Samaras disclaims in his deposition testimony he offers any "opinions that are medical." *Cf. Rowland*, 9 F. Supp.3d at 569 (concluding prescribing physicians could testify as to label and warning adequacy).

C. Samaras's Opinions on Pharmacovigilance, Risk Management, and Quality Management Will Not Be Excluded

i. Qualifications

Defendants contend that Samaras's lack of regulatory expertise with prescription drugs also makes him unqualified to assess the adequacy of Defendants' pharmacovigilance practices in respect to Injectafer, a category Defendants apparently use to refer broadly to Samaras's opinions on "pharmaceutical risk management," "pharmacovigilance system[s]," and "[q]uality [m]anagement [s]ystem[s]." Plaintiff responds that Samaras's broad experience in risk management with respect to regulated organizations "translates to pharmacovigilance in a pharmaceutical context" and qualifies him to opine on pharmacovigilance and risk management concerning drug products because, as Samaras explains in his deposition testimony, "'pharmacovigilance' is a science that is equivalent to risk analysis and risk management solely focused on drugs. So 'pharmacovigilance' is a subset of risk management[.]"

Samaras's experience and qualifications in risk management and human factors engineering qualify him to opine on Defendants' pharmacovigilance, risk management, and quality management systems. Samaras has "designed, developed, analyzed, and audited quality management systems for industry clients," including in "a variety of postmarket activities, with an emphasis on postmarket risk management." He has "extensive experience (nearly four decades) working with regulated organizations," and is "qualified (and nationally certified) to both design/analyze . . . and audit . . . the quality management systems and compliance of medical product manufacturers." Moreover, he has published extensively on "design controls, risk analysis, human factors engineering, [and] quality engineering[.]"

To the extent that Defendants dispute Samaras's qualifications as to pharmacovigilance on the basis he lacked certain knowledge at his deposition related to "pharmacovigilance-critical

regulations," *e.g.*, "Periodic Safety Update Reports" and "Periodic Adverse Drug Event Reports," such criticisms are better suited for cross-examination. *See, e.g.*, *QVC, Inc. v. MJC Am., Ltd.*, 2012 WL 13565, at *3 (E.D. Pa. Jan. 4, 2012) (stating that concerns about expert qualifications that "relate more to the weight" of the testimony should be subject to the adversarial process (citation omitted)).

ii. Reliability

Samaras bases his pharmacovigilance, risk management, and quality management conclusions on his review of relevant documents in this case—including medical publications, corporate documents, documents provided to him by Plaintiff's counsel, and relevant portions of Defendants' experts' testimony—through the lens of his experience in risk and quality management for regulated organizations. Samaras thus relies on his "experience and knowledge in analyzing the available information," which is "an appropriate methodology for a pharmacovigilance expert." *In re: Tylenol (Acetaminophen) Mktg., Sales Pracs., & Prod. Liab. Litig.*, 2016 WL 4039286, at *5 (E.D. Pa. July 28, 2016). Additionally, Samaras appears to base his conclusions on "customs and business practices in the industry in which he works"—*i.e.*, risk and quality management for regulated companies. *See T.N. Incorporation*, 2021 WL 5980048, at *15 ("[A]n expert is permitted to base his opinions on the customs and business practices in the industry in which he works."). On this basis, Samaras's opinions on pharmacovigilance, risk management, and quality management are based on a sufficient factual foundation and supporting methodology.

Defendants challenge the reliability of Samaras's pharmacovigilance opinions on various grounds, including: his method of finding sample case reports; his "broad-brush" criticisms of pharmacovigilance practices, using words like "passive" and "voluntary" to describe

Defendants' practices; and the absence of a "threshold review of the elements of [Defendants'] pharmacovigilance program" similar to that conducted by Defendants' expert, Dr. Amy Gartland Egan. These criticisms are better suited for cross-examination. *See id.* at *17 (concluding argument that expert should have reviewed further documentation was an issue "better suited for cross-examination at trial"); *United States v. Mitchell*, 365 F.3d 215, 244 (3d Cir. 2004) ("As long as an expert's scientific testimony rests upon good grounds, based on what is known, it should be tested by the adversary process[.]" (quoting *Ruiz–Troche v. Pepsi Cola of Puerto Rico Bottling Co.*, 161 F.3d 77, 85 (1st Cir. 1998)) (internal quotation omitted)); *Hausknecht*, 2022 WL 1664362, at *8 ("Where an expert witness has 'some factual basis—albeit shaky' to support his opinion, the proper solution is to allow an adverse party to 'highlight those weaknesses through effective cross-examination.'" (quoting *Stecyk v. Bell Helicopter Textron, Inc.*, 295 F.3d 408, 414, 415 n.3 (3d Cir. 2002)).

iii. Fit

Defendants make no argument that his opinions on pharmacovigilance do not fit the facts of the case. In any case, his opinions on pharmacovigilance, risk management, and quality management are relevant and have a connection with the "particular disputed factual issues in the case." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d at 743 (quoting *United States v. Downing*, 753 F.2d 1224, 1237 (3d Cir. 1985)). For instance, Plaintiff's negligence claim is predicated on Defendants' allegedly inadequate "testing, monitoring, and pharmacovigilance of Injectafer."

For the reasons above, Samaras's opinions on pharmacovigilance, risk management, and quality management will not be excluded, but his opinions on the adequacy of Injectafer's prescription drug labeling will be excluded as well as any opinions drawing legal conclusions.

An appropriate order follows.

BY THE COURT:

/S/WENDY BEETLESTONE, J.

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WENDY BEETLESTONE, J.